



# TSCA 8(e) Substantial Risk

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# Overview

Statutory Language

Parsing the Terms - Elements of Proof

Famous Cases

- DuPont PFOA

- DuPont Inhalation

- Elementis



Grand Finale

A little  
wild





FROM Gets  
Famous



8(e) Is the Early Warning  
System for Finding Toxic  
Chemicals Impacting Our  
Health and Our Families





Must enforce the statute –  
there are no rules for TSCA §  
8(e).

OPPT provided guidance in  
1991 and 2003 plus periodic  
Q's & A's.

EAB Elementis is the only  
case law on TSCA § 8(e).

“Any Person who manufactures,  
processes, or distributes in commerce a  
chemical substance or mixture and who  
obtains information which reasonably  
supports the conclusion that such  
substance or mixture presents a  
substantial risk of injury to health or  
the environment shall immediately  
inform the Administrator of such  
information unless such person has  
actual knowledge that the  
Administrator has been adequately  
informed of such information.”

**Obtains information about  
such chemical**

Does NOT need to be a completed study !

# Person who manufactures, processes or distributes in commerce a chemical



Is R&D without going into production enough?

◆ **Statue of limitations runs when violation accrues.**  
Accrues when EPA is informed of the information.

◆ NOT upon completion of study

◆ NOT necessarily upon submission of study to EPA.



# **The information reasonably supports the conclusion that such chemical presents a substantial risk of injury to health or the environment**

## **EPA 's 2003 Guidance on "What Constitutes Substantial Risk"**

**A ``substantial risk of injury to health or the environment'' is a risk of considerable concern because of (a) the seriousness of the effect . . . , and (b) the fact or probability of its occurrence. (Economic or social benefits of use, or costs of restricting use, are not to be considered in determining whether a risk is ``substantial.") These two criteria are differentially weighted for different types of effects. The human health effects listed in subpart (a) of this part, for example, are so serious that relatively little weight is given to exposure: The mere fact the implicated chemical is in commerce constitutes sufficient evidence of exposure.**

## **Substantial Risk**

**Risk = Toxicity X Exposure [Exposure assumed for highly toxic chemicals.]**

**Does the 1991 toxicity range chart apply to the 2003 Guidance? (See Q&A 15 – Will the chart apply to all chemicals over the full period of non-reporting?)**

**Should highly toxic chemicals receive different penalty than moderate or low toxicity chemicals?**

**EPA has never made a distinction between vapors & droplets for inhalation. DuPont created its own scientific basis to handle droplet inhalation differently from 1991 toxicity guidance chart.**

**Many chemicals were not marketed and thus no exposure to support a substantial risk**

**Shall immediately inform Administrator of such information**

“immediately” not defined by statute

“inform the Administrator” not defined by statute

2003 Guidance & Q & A's issued after 2003 indicate 30 days to either publish the information or provide EPA with a summary of it.

**Unless such person has actual knowledge that the Administrator has been adequately informed.**

OPPT disagrees with DuPont on some interpretations of known to the Administrator.

Is the Administrator informed when the chemical's MSDS sheet includes the LD50?

Is testing the same product with slightly different composition providing new information or corroborating previous test?



# Famous Cases Involving 8(e)

(b)(7)(A)

Dupont PFOA,  
DuPont Inhalation  
Elementis

**The Only Case Where the  
OPPT Office Director  
Wrote a Statement that  
the Failure to Report  
Disrupted EPA's  
Regulatory Process**

**DuPont PFOA**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

APR 12 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: DuPont Submission

FROM: Charles M. Auer, Director *Charles M. Auer*  
Office of Pollution Prevention and Toxics

TO: Walker Smith, Director  
Office of Civil Enforcement

On March 20, 1981, 3M Corporation provided the Agency with a TSCA Sec. 8(e) submission on a 1980 rat developmental toxicity study concerning an eye abnormality in rats exposed to PFOA. On March 12, 1982, the Agency met with 3M and DuPont regarding subsequent studies they had undertaken to provide better information on the significance of the eye defect in the 1980 developmental toxicity study. While the new information clarified questions about the nature of the observed eye defects in the rat developmental toxicity study, there were lingering questions in EPA about whether the available information provided an adequate hazard characterization of the developmental toxicity potential of PFOA. The Agency's process at the time for determining the priority of testing activities required a review of the available information by an Office hazard assessor to inform a recommendation for whether additional testing was needed. The Office hazard assessor, a Ph.D. reproductive toxicologist, recommended that additional testing be conducted on perfluorochemicals to more fully address the outstanding questions due to the potential for human exposure to PFOA and other



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In March 2001, EPA received from a third party information indicating that as early as May 14, 1981 (a date which is approximately 2 months after EPA's receipt of the 3M Sec. 8(e) submission), DuPont had information that indicated that they had found PFOA in the blood of female DuPont workers and in umbilical cord blood from an infant born to a female worker, indicating human transplacental movement from an exposed mother to a newborn. The information also reported possible eye defects in the offspring of female workers. If the Agency had received this information when it was obtained by the company in 1981, as required by TSCA Sec. 8(e), it would have provided a more complete picture of the potential hazards associated with human exposure to PFOA and would likely have resulted in elevating the priority for further testing of PFOA and other perfluorochemicals in the early 1980s. It is also likely that the Agency would have promptly referred this information to OSHA and NIOSH due to potential

Found Here



# PFOA Litigation

## E.I. Dupont de Nemours and Company – Dec. 21, 2005

- §8(e) Substantial Risk Information

- DuPont failed to inform the Agency for nearly 20 years that PFOA crossed the placenta at very high rates.
- EPA and DuPont entered into a **\$16.5 million** settlement that included:
  - payment of a \$10.25 million penalty, the largest administrative penalty in EPA's history,
  - \$5 million in research on PFAS
  - \$1.2 million to local schools for updated chemistry

<https://www.epa.gov/enforcement/ei-dupont-de-nemours-and-company-pfoa-settlements>

The Devil We Know

# DuPont Inhalation 8(e)

**Largest 8(e) Case Involving Animal Studies**

## DuPont “compromise” at 57 reporting obligations

29 Extremely Toxic

28 Moderately Toxic or Low Toxicity (Exposure considered.)

## EPA found perhaps 104 studies are reportable

(depending on exposure facts; the difference in composition of the same product tested; whether tremors is enough for substantial risk; at what point there was intent to use as pesticide; etc.).

DuPont identified 210 day period from PFOA settlement to inhalation disclosure as reasonable time frame to calculate penalty-- \$3.3 Million Settlement Agreed To



Elementis

# TSCA New & Existing Chemicals Appellate Decision on Statute of Limitations

## Elementis Chromium Appeal

- ◆ Environmental Appeals  
Board Decision
  - ◆ EAB reversed a penalty  
of \$2,571,800 based on  
§ 8(e) Guidance  
statements
  - ◆ EAB clarifies SOL  
position that 8(e) is a  
continuing violation



# Elementis Chromium Inc.

EAB's finding :

- 1) the Agency's TSCA § 8(e) guidelines are much more limiting than the statute and that some reporting obligations are unclear,  
and
- 2) some TSCA §8(e) reporting obligations can be continuing violations and not subject to a statute of limitations (SOL) for enforcement actions.

EAB reversed on March 13, 2015, the \$2.3 million ALJ ruling on penalty due to EPA guidance issues while holding Elementis violated TSCA § 8(e) and the complaint was timely filed.

SOL issue: All days of violation within 5 years of complaint can be included in penalty calculation; maybe more depending on the situation

TSCA § 8(e) Guidance issue: Only “more serious” adverse effects (cancer at lower dose or cancer more quickly) would require reporting under the guidance and exempts this epidemiology study showing modern facilities with new, valuable and different information (albeit supporting substantial risk) concerning the dose-response relationship between hexavalent chromium and lung cancer of workers.



(b)(7)(A)

Multiple PFAS Chemicals at multiple sites. If there is widespread releases of these PBT chemicals at some point became information not known to EPA

*The End*